

REMARKS

Applicants wish to thank Examiner Epps-Ford for kindly granting a very helpful telephonic interview on March 30, 2007 with applicants' representative (Mr. Kenneth Sibley), a representative of the licensee (Dr. Indu Parikh) and licensee's counsel (Ms. Jayme Huleatt).

Applicants respectfully request reconsideration of the present application and entry of this amendment after final rejection in view of the foregoing amendments, the discussion during the telephonic examiner interview as summarized below, and in view of the reasons that follow.

Upon entry of this amendment, claims 85, 88, 89, 91 - 93, and 116 - 120 will be pending, claims 85, 88, 91 and 116-120 are currently amended and claims 86, 87, 101 - 105, 107 - 109, 111, 112, and 121 - 135 are canceled in this response. Claims 1 - 84, 90, 94 - 100, 106, 110 and 113 - 115 were previously canceled during the course of prosecution in this application. The canceled subject matter has been canceled without prejudice or disclaimer. Applicants reserve the right to file any canceled and unclaimed subject matter in one or more continuing applications. This amendment is fully supported by the originally-filed application, i.e., see page 12, lines 8 - 15, the paragraph bridging page 9 -10, and original claim 19.

As discussed, Claims 85 and 91 have been amended to combine subject matter of claims 101 and 107, respectively, to include the MANS peptide and N-terminal myristoylated fragments thereof in one method and one formulation claim. Claims 85 and 91 also have been amended to more clearly recite the N-terminal myristoylated peptide fragments of the MANS peptide, SEQ ID NO: 1 as suggested by the Examiner. Claim 85 additionally has been amended to recite that the treated subject is suffering from asthma. Claim 88 is amended to correct antecedent basis language. Claims 116 - 120 recite specific N-terminal myristoylated peptide fragments of MANS peptide by their minimum size.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. To reiterate, after amending the claims as set forth above and entry of this amendment, claims 85, 88, 89, 91-93, and 116 - 120 are now pending in this application. No new matter has been added.

I. Rejection under 35 U.S.C. § 112, second paragraph

Claims 116-121 are rejected under 35 U.S.C. § 112, second paragraph as allegedly failing to distinctly claim the subject matter of the present invention. The Examiner states that the language of these claims recites ranges that lack sufficient antecedent since these ranges allegedly have no upper limit, and therefore, are broader in scope than independent claims 85 and 91 from which they depend. Although not acquiescing to the Examiner's basis for this rejection, applicants have as discussed amended claims 85 and 91 to delete the recited range language in defining the N-terminal myristoylated peptide fragments of MANS, and therefore submit that claims 116-120 now recite the lower range of the specifically claimed peptide fragments of MANS which is the upper limit.

II. The presently claimed invention is enabled for the full scope of the claimed invention

Claims 85-89, 101-105, 116, 118, 120 and 122-135 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled for the full scope of the claims. To support this rejection, the Examiner states that while she considers the specification enabling for inhibiting mucus secretion *in vitro*, and for decreasing mucus hypersecretion *in vivo* via airway administration of the MANS-peptide or active fragments thereof comprising at least the first 10 amino acids of the MANS-peptide in a mouse model of asthma, she does not consider the specification enabling for the *in vivo* therapeutic treatment of bronchitis, cystic fibrosis, chronic obstructive pulmonary disease comprising administration of the compounds of the present invention.

Applicants maintain that the *in vivo* mouse model provides reliable data to study the inhibition or reduction in mucus hypersecretion as a clinical symptom in a number of respiratory and pulmonary diseases in which mucus hypersecretion is a major clinical symptom. The Examiner suggests that applicants' own specification supports her position that there is unpredictability associated with regulating mucus secretion. However, applicants believe that they have provided sufficient evidence and arguments to support their position that the method claims of the present application should be of a sufficient breadth to reduce MARCKS protein-related mucus hypersecretion as a clinical symptom of any of the above mentioned diseases.

However in an effort to expedite prosecution, and to obtain allowable subject matter, applicants have amended claim 85 as discussed to recite that the subject treated is suffering from asthma. Additionally, applicants have amended claims 85 and 91 to recite the N-terminal myristoylated peptide fragments to clearly define the peptides that are useful in the present invention. Applicants reserve the right to file one or more continuing applications on any canceled subject matter. Therefore, in view of the claim amendments, it is respectfully requested that the Examiner withdraw the lack of enablement rejection of all of the pending claims

III. Obviousness-type Double Patenting Rejection

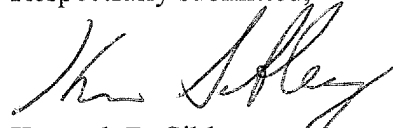
Claims 85-89, 91-93, 101-105, 107-109, 111-112 and 116-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-54, 57-67, 70-75 and 85-91 of co-pending U.S. Serial No. 10/802,644 ("the '644 application"). The Examiner states that this rejection is provisional and can be withdrawn if it is the only remaining rejection of record. As applicants believe that this rejection will be the only rejection remaining after the entry of this amendment, applicants request that the Examiner withdraw this obviousness-type rejection.

CONCLUSION

In view of the remarks, claim amendments presented herein and the issues discussed during the telephonic interview with the Examiner, it is believed that the present set of claims are now in condition for allowance. Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a further telephonic conference would expedite any minor issues with regard to the pending claims, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. § 1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully submitted,



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